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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,075	07/19/2001	Jean Barbeau	955.117USWO	8384

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EXAMINER

WINTER, GENTLE E

ART UNIT	PAPER NUMBER
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1746

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,075

Applicant(s)

BARBEAU ET AL.

Examiner

Gentle E. Winter

Art Unit

1746

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1746

Detailed Action

Claim Rejections - 35 USC § 112--Withdrawn

1. Claims 42 and dependant claims 45-46, 48 and 71 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendments and arguments have overcome or obviated the rejections.

Claim Objections--Withdrawn

2. Applicant's corrections and clarifications have corrected the indicated deficiencies.

Response to Arguments

Applicant argued:

The '275 reference is restricted to a few compositions that are disclaimed from the present claims and, as the Examiner points out, the '275 patent fails to explicitly disclose a composition outside the indicated excluded range. Applicants respectfully submit that there is no teaching or suggestion in the '275 reference of how specific components attack the integrity of the biofilms, e.g. there is no mechanism of action proposed that would lead to the establishment of a generic class of components useful for the purpose of removing biofilms with high efficacy.

3. It is noted that the argument as to motivation need not be exactly the same as the applicants'. The requisite motivation is explicitly provided in the references themselves, namely the artisan would have been motivated to select a quantity of SDS, which has the requisite lysing efficacy. The SDS is integral to the creation of holes in the cell membranes.

4. The reference recited proportion (1.4:1) ties protein denaturing efficacy with SDS concentration. For example Nishiguchi discloses a DNA extraction protocol utilizing a 0.1% SDS, NaCl, and EDTA.

Art Unit: 1746

Applicant argued:

The present disclosure, on the other hand, teaches that efficient biofilm removing solutions can be minimally composed of a detergent and a salt-forming acid at a working pH. The action of the salt, monovalent sodium in the preferred case, is to replace the divalent calcium involved in maintaining the integrity of the exopolysaccharides (EPS), the "sticky" constituent of biofilms. The present disclosure reports a large number of acids that support this conclusion. Furthermore, the present disclosure teaches that a compound having bactericidal properties may be added to the minimal detergent plus salt-forming acid if a biofilm-removing bactericidal composition is desired.

Art Unit: 1746

While the recitation "being capable of" is not the same as the active recitation "removing" even if there were such a teaching, the same is inherent in the references which disclose the same composition.

This examiner finds it noteworthy that applicant is arguing that the reference disclosed narrow range does not contemplate anything outside the range. Seemingly, varying compositions would result in a gradual change in efficacy. The prior art discloses the matter explicitly except for the disclaimed composition. Applicant has added "about" to modify the disclaimed components, but doing so only adds to the confusion as to what IS claimed, now it is known what is "about" not claimed but it is not clear what is claimed. The fact that compositions of the method are so close to the claimed solution suggests that the discovery is really little more than exactly what would have been expected.

It is also noteworthy, that applicant's claim 1 is drawn virtually any soap and salt composition that is contacted with a biofilm.

Applicants respectfully disagree because the cited references pertain to totally different problems that are not related to dislodging biofilms. Indeed, biofilms are complex associations of cells, extra cellular products and detritus either trapped within the biofilm or released from cells that have lysed as the biofilm aged. The main "cement" for all these cells and products is the mixture of exopolysaccharides (EPS) secreted by the cells established within the biofilm. The removal of the latter therefore requires attacking the integrity of the exopolysaccharide matrix where divalent calcium, hydrogen bonding and hydrophobic forces are involved in linking these polymeric chains together. As indicated above, the present disclosure teaches the generic minimal composition of a detergent and a salt-forming acid to the dismantlement of biofilms. The disclosure also teaches the possible adjunction of a compound having bactericidal properties to obtain a generic bactericidal biofilm dislodging composition.

It is not clear if applicant is suggesting that the composition that is used in is not identical to that claimed or if the motivation for making the combination is lacking. In either case the composition is disclosed, so is the use, namely for removing biological films. AS such the motivation, as set forth in the Official action is deemed appropriate and, unfortunately, the arguments are not persuasive at this time and the rejection is made final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 68, 70 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,910,420 to Tuompo. The SDS-PAGE system which is well known in the art relies on an inter alia 0.1% SDS, EDTA, salt solution. See *inter alia* column 3, line 37 *et seq.* and see e.g. column 7, line 19 *et seq.* Applicant's claim amendments have necessitated a new ground of rejection. The method is drawn to removing biofilms. The current claims do not address whether the biofilms are left intact or destroyed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 41-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 5,731,275 and Applied and Environmental Microbiology by Nishiguchi et al. (Nishiguchi)

Art Unit: 1746

6. With respect to claims 41-80 drawn to a method for removing a biofilm from a surface, which comprises the step of contacting said surface with a composition comprising an effective dislodging amount of a detergent and an effective dislodging amount of a salt forming acid, said salt being capable of displacing divalent cations present in the structure of said biofilm, for a time sufficient to dislodge said biofilm, all percentages representing weight per volume concentrations. With the proviso that said composition is not a mixture achieving an aqueous final concentration of SDS 1 % - 2 % and EDTA 1%, or SDS 1% - 2% and mandelic and lactic acids, each at an individual concentration of 1% or in a combined concentration of 2%. The '275 reference identically discloses each and every limitation of claim 41 except that the '275 patent fails to explicitly disclose a composition outside the indicated excluded range. See e.g. column 3, line 29 *et seq.*

7. Sodium dodecyl sulfate (SDS) is an anionic detergent with a long hydrophobic tail that binds to the hydrophobic side chains of amino acids at a constant ratio of 1.4g of SDS to 1g of polypeptide, proportional to the molecular weight of the protein (Hames, 1998). The artisan would have been motivated to select a quantity of SDS, which has the requisite lysing (aid) efficacy. The SDS is integral to the creation of holes in the cell membranes.

8. The above recited proportion (1.4:1) ties protein denaturing efficacy with SDS concentration, admittedly this may periodically include a 1-2% SDS solution but it need not. For example Nishiguchi discloses a DNA extraction protocol utilizing and 0.1% SDS, NaCl, and EDTA.

9. The motivation for modifying the references is in the references and in the knowledge generally available to one of ordinary skill in the art. Specifically, the primary reference

Art Unit: 1746

discloses that the disclosed composition is the preferred composition. The prior art of record is replete with teaching showing the interrelationship between the concentration of SDS and cleaning efficacy and the secondary reference actually teaches the claimed composition for the purpose of denaturing proteins a critical step in the biofilm removal process of the '275 patent.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. United States Patent Nos. 5,942,480, 5,759,970 both disclose all of the limitations of the instant invention with the exception of failing to disclose a range outside the excluded range.

14. The addition of "about" confuses the issue as to what applicant regards as the claimed invention. Now the claim recites that the invention's composition is not "about" what is

Art Unit: 1746

disclosed in the prior art of record. Applicant is trying to claim what the invention is not rather than what the invention is.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gentle E. Winter whose telephone number is (703) 305-3403.

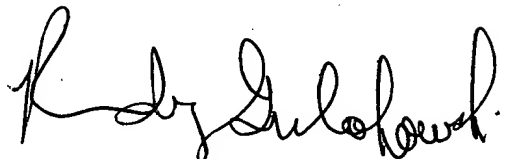
The examiner can normally be reached on Monday-Friday, 8:30-5:00..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (703) 308-4333. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Gentle E. Winter
Examiner
Art Unit 1746

September 16, 2003


RANDY GULAKOWSKI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700